

Appl. No. 10/707,921
Amdt. Dated January 6, 2006
Reply to Office Action of October 6, 2005

Remarks

Claims 1-16 remain in the application. Claims 1-15 are original. Claim 16 is new.

Claim Rejections – 35 USC §102(b)

The Office Action states a rejection of claims 1-15 under 35 USC §102(b), citing applicant's website <http://net1device.com>. Applicant respectfully traverses this ground for rejection. The Office Action encloses no supporting document for this rejection; nor does it state what age or version of the website the Office is relying upon.

In the absence of a new cited document or new citation of the website, applicant's own IDS having a mailroom date of March 1, 2004, appears to be the only available version of record. A review of this IDS submission shows no mention of the NET-1000. However, the Office Action makes specific reference to "the disclosure of the NET 1000 device as referenced on the website. . . ." Since applicant's submission for purposes of the IDS did not include the NET-1000 device "as referenced on the website," applicant requests clarification and a copy of whatever other document or material the Office believes to qualify as a bar under 35 USC §102(b).

No website disclosure of the NET-1000 was made in a time frame more than one year before the filing date of the present application. As corroborated proof of this fact, applicant submits the following declaration into evidence:

Located in the appendix, **Declaration of Jim Goebel Under 37 CFR 1.132** analyzes the archived history of the website, as recorded on archive.org. Exhibits to this declaration are taken from the archive site to corroborate this analysis. The analysis demonstrates that the NET-1000 appeared on the website months after, *but not before*, the filing date of the present patent application. Thus, no bar under §102(b) appears to be present.

As a further consideration, applicant has speculated that the Office may have misinterpreted the significance of the copyright notice on applicant's current website. The copyright notice lists the year 1998. Should this be a source of misunderstanding, please take notice of long-established copyright practice wherein the year shown in a copyright notice is the year of first publication of the basic work, regardless of later additions and revisions. The copyright year notice does not indicate the publication year

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for every item of content. The current website properly may add the NET-1000 without requiring a changed year in the copyright notice.

The above showing is based upon applicant's best interpretation of the Office Action. In light of the evidence, applicant requests that the rejection under 35 USC §102(b) be withdrawn. If any remaining basis for the rejection prevents withdrawal of the rejection, applicant requests clear and specific identification of the remaining basis.

Claim Rejections – 35 USC §103(a)

The Office Action states a rejection of claims 1-15 under 35 USC §103(a), citing patents to Kim, Colsen, and McCall '838. Applicant reviews these references, below, for sufficiency in anticipating the invention.

KIM:

The patent to Kim is cited for teaching a stimulus generator, ear contact assembly, impedance detector circuit, and sonic annunciator for reporting impedance levels. Although these individual features are present in Kim, their functional arrangement is significantly different from that disclosed and claimed in the present application. Applicant combines and operates these features in a new way to enable a new result and solve a long-standing problem.

Applicant offers his declaration, which is appears in the appendix as **Declaration of Onjé Erfan, M.D., Under 37 C.F.R. 1.132**. Although this declaration primarily addresses the Colsen reference, it also provides insight into applicant's purpose of creating a self-administrable treatment device. One can speculate that self-administration is always a possibility with any treatment device, regardless of whether such a step is wise or safe. Applicant presents the sub-issues that self-administration should enable (1) consistent, (2) safe, and (3) effective treatment. As will be further pointed out below, applicant overcomes known problems to satisfy these issues.

Specifically, applicant provides consistency by carrying the earpieces with the protrusions that present the electrodes in a suitable arrangement to be self-guiding. The electrodes will contact the desired treatment area with consistency. Applicant further provides consistency by enabling the electrodes within an array to transmit signals between and among themselves, without requiring a separated ground electrode at a remote location. Applicant provides safety by the self-guiding feature, so that the electrodes do not contact or stimulate undesirable or potentially harmful areas of the ear.

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Applicant provides improved effectiveness of treatment by enabling the electrodes to transmit signals over a variety of signal pathways, for trans-cranial treatments as well as other treatment modes.

Applicant overcomes the related problem of making a treatment device reasonably available to those who desire it. A significant obstacle was the need in the prior art to custom fit each earpiece to the patient, which resulted in considerable professional time and cost of technicians, lab work, and the like. As evident from the drawings, the invention is a standardized headset, such as a molded and mass-produced headset capable of fitting substantially any ear. Hence, it is against the background of making a standardized headset that applicant also has solved the problems of consistency, safety, and effectiveness.

The specific differences from Kim result from applicant's stated purpose, also recited in the claims, of creating a neuro-electric-therapy headset that is self-administrable. Applicant's headset should be reasonably automatic in its fit to the treatment location on the patient's ears. Applicant's headset is structured to ensure proper placement and operation without requiring that the headset be custom crafted to each patient.

According to Kim, each earpiece is custom crafted to the patient's specific ear (col. 6, line 6). Thus, Kim teaches the need to individually locate the treatment points on each patient's ear and custom position the electrodes (col. 6, lines 3-8) on a custom built earpiece for each patient. Kim calls for a "treating physician" (col. 5, line 39) to administer and monitor treatment. Where Kim discloses an impedance detector circuit (col. 5, lines 59 et seq.), Kim describes an impedance-sensing probe that operates from the signal generator. Despite the fact that Kim provides no detailed disclosure and no drawing of the probe, it is clear that the probe is physically distinct from the treating earpiece electrode. This is established by Kim's description of a specially configured probe tip that is a different entity from the contact points (5) and (6) used during treatment. Since Kim's contact points (5) and (6) are placed directly on the treatment points during treatment, it is clear that Kim's impedance sensing probe cannot be in simultaneous contact with these same points. As a necessary conclusion, Kim teaches that the impedance-sensing probe is a different entity from, and used at a different time than, the treatment contact points on the earpiece.

Applicant's headset significantly differs from Kim's in order to carry out its self-administrable function, more fully discussed above. Paragraph [0052] discloses that applicant's audible signal confirms that the tissue interface circuits, i.e. the electrodes (56), are in contact with an area of the ear having suitable low impedance. The impedance-sensing function of applicant's headset operates through the same electrodes (56) as the treatment signal. This utilization of the electrodes (56) for both purposes is enabling of self-administration. In order to self-administer, the user applies the headset and then confirms

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via the impedance sensing function that the electrodes are properly positioned. Kim could not equivalently carry out this function, since Kim employs a probe that is separate from the electrodes (56). Thus, once the electrodes (56) are in proper position, both the audible confirmation and the treatment can follow with no further need to remove, reapply, or reposition the electrodes. Kim teaches no means to confirm proper placement of the earpiece electrodes after they have been applied.

If the user wished to confirm proper placement of Kim's electrodes on the ear, doing so with certainty is not possible. The user could apply Kim's integrated impedance probe, although it would require first removing or not wearing the earpieces. Thereafter, the user would attempt to apply the earpieces to the points determined by the probe, but there is no assurance that the resulting placement is accurate. Kim provides no real-time method for the user to subsequently know that he has properly applied the headset. Thus, applicant solves problems that exceed Kim's teachings. It cannot be said that Kim makes obvious applicant's invention.

COLSEN:

The Office Action cites Colsen in combination with Kim, as supplying the teaching of a combined therapeutic sound generating device and electrical acupuncture device. Colsen states that the device can be self-administered. As noted, above, stating that a device might be self-administered does not answer the ultimate inquiry. Questions of consistency, safety, and effectiveness must be answered.

In evaluating Colsen for adequacy in formulating an obviousness rejection, the weight accorded to Colsen's teachings must be tempered by the scope of those teachings and their compatibility with the primary reference –Kim – and to a lesser degree, McCall. If Colsen's teachings are incompatible with Kim and McCall, there would be no motivation, and hence no proper basis, for an obviousness rejection based on their combination.

To the extent Colsen's treatment is self-administered, significantly the treatment is not applied to any predefined treatment area, showing a problem in consistency. Colsen provides no improved method of delivering treatment to specified points, such that the method can be reasonably adapted for use with Kim or McCall. This raises issues of consistency and effectiveness. Colsen provides no apparatus that can be adapted to the Kim or McCall apparatus, raising the legal issue vis-à-vis the obviousness rejection: would those skilled in the art would find reason to try.

Colsen addresses the consistency problem of applying an electrode to a distinct point or area by simply NOT locating any point or area and NOT applying any apparatus or electrode to a specific point. Instead, Colsen applies a blanket treatment over a vaguely

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defined electrified zone, asserting treatment of any points that happen to fall within the zone. Colsen alleges to establish a broad electrified zone between an electrode at the ear canal and another electrode clipped to the helix of the ear. This suggested method of treatment raises considerable issues of consistency, safety, and effectiveness. The electrode on the helix can be attached to the user's auricle "at any desired location." (Col. 5, line 65) The resulting lack of control or definition of the points that receive electrical stimulation creates further issues of consistency, safety, and effectiveness. Significant to the question of combining Colsen and Kim in an obviousness rejection, Colsen's electrified zone cannot be reconciled with Kim's point treating methods.

In contrast, Kim fastidiously locates treatment points and precisely applies electrodes in direct contact with those points. McCall is similar. To combine Colsen with Kim and McCall is to abandon the teachings of Kim and McCall regarding essentials of how to deliver treatments. Colsen's method of achieving self-administration is clearly incompatible with the other references. It is well accepted that in making an obviousness combination, the claimed combination cannot change the principle of operation of the primary reference or render the reference inoperable for its intended purpose. See MPEP 2143.01 VI. In this case, Colsen is not an appropriate component of an obviousness combination with Kim or McCall.

The inventor's declaration, **Declaration of Onjé Erfan, M.D., Under 37 C.F.R. 1.132**, provides further evidence. This declaration corroborates the above observations that the technology taught in Kim and McCall is premised upon the accurate location of electrodes to contact precise treatment locations. The declaration provides the additional information that would be significant to those skilled in the art: clinical reports have mentioned the stimulation of certain points at the ear canal to be associated with harmful events. These include cardiac irregularity and spontaneous abortion. Thus, it is clear that those skilled in the art would find significant reason to NOT to follow Colsen's teaching for self-administration by creating an electrified zone between ear canal and helix of the ear. Such a zone is of imprecise size and boundary. It is unknown what points are stimulated. Thus, a treatment method requiring such an electrified zone carries a possibility of being inconsistent, unsafe, and ineffective. It cannot be reliably concluded that the Colsen reference truly solves the problems of self-administration.

Due to the inherent conflict of treatment method between Colsen and the other references, Colsen cannot reasonably be combined to make the obviousness rejection suggested in the Office Action. Applicant respectfully requests that the rejection be withdrawn.

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McCALL:

The Office Action cites McCall in combination with Kim and Colsen in formulating an obviousness rejection, wherein McCall teaches an earpiece with an elongated protrusion (10). It should be noted that McCall's protrusion (10) is essentially a loose part, unsupported by any carrying structure. As a "loose part," it is not equivalent to applicant's protrusion that is carried on a headset in a manner specifically designed to guide the earpiece's electrodes into contact with a desired area of an ear.

McCall's protrusion, which McCall refers to as an ear mold housing (10), "is to be formed individually by making an impression from the particular patient." (Col. 2, lines 46-48) As a custom made device, McCall's protrusion (10) provides no useful answer to the problem making a standardized, self-administrable headset. Notably, the prior art such as Kim and McCall rely upon the custom fitting of each earpiece to provide consistent application of electrodes against treatment points. Even if it were assumed, *arguendo*, that the housing (10) might be mounted on a headset band, the prior art fails to teach any mounting structure that would automatically applies the housing (10) to a specifically desired area in the conch of the ear.

At paragraphs [0047] – [0048], applicant discloses a protrusion (54) or frusto-conical trunk that carries electrodes (56) that occupy substantially the entire free end of the protrusion. This protrusion is part of a headset structure designed to deliver the electrodes against Arnold's branch of the Vagus nerve, on the ear of substantially any patient. Thus, an important feature of the protrusion is that it is not individually crafted to fit the particular patient. Instead, as best shown in Fig. 7, it is a guiding element (paragraph [0037]) that delivers the electrodes with consistent accuracy while not required to be a custom part.

The disclosure provides detailed guidance on how applicant's protrusion (54) is best carried on the headset. Paragraphs [0037] and [0039] disclose that the headset carries the protrusion with a slight downward and, optionally, rearward angle. Because the protrusion is mounted on a headset, these angles can pre-dispose the protrusion to properly enter the conch of a human ear. The pre-disposed angles enable the headset to be self-locating for self-administration. Of course, the self-administration is for a method of direct contact treatment applied to a selected area, which distinguishes from the non-direct-contact zone treatment that Colsen teaches. Thus, even if others in the art could adopt Colsen's technique for self-administration, the technique still would be distinguishable in structure and function, as previously pointed out, in detail. McCall's lack of any supporting headset renders moot the issue of whether McCall's housing (10) anticipates the self-administration of direct contact treatment.

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Additional optional features of the headset further enable self-administration. Paragraphs [0043] and [0044] disclose pivot rings (30, 34), guide slot (42) of each earpiece, and a pivot limiting means. These pivot structures position the protrusion (54) for accurate entry into the conch of an ear. Thus, McCall's housing (10), being a non-supported or loose component, cannot be fairly equated with applicant's protrusion (54) as a suitably supported component of a headset.

CLAIMS:

The main claims are distinguished from the prior art. Specifically, independent claims 1 and 12 contain one or more elements that individually and separately cause them to be novel and non-obvious over prior art of record:

Claim 1 recites, "wherein said tissue interface circuits are in communication with said waveform source device for communicating impedance and receiving treatment signals. . . ." As discussed in distinguishing from Kim, the ability of the earpiece electrodes to both communicate impedance and deliver treatment signals is enabling for a self-administered treatment. Kim requires separate application of the impedance-measuring probe.

Claim 1 further recites the structure of elongated protrusions that are portions of a headset and "arranged for applying the respective tissue interface circuits against the conch of a human ear when the headset is applied to a human subject. . . ." As discussed in distinguishing from McCall, McCall's housing (10) is essentially a loose part, free of any headset carrier to aid its application against the conch of an ear. Applicant's appropriate predisposition of the protrusion solves a problem and better enables self-administration.

Claim 12 recites a method step of providing a "headset carrying a selectively activated waveform source device with simultaneous impedance measuring means . . ." and "delivering effective waveform treatment . . . while simultaneously generating . . . an audio output signal responsive to measured impedance . . ." This improvement over Kim was previously discussed and enables self-administration.

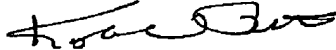
A new claim 16 is added, dependent from claim 12. This claim relates to trans-cranial treatment. Although Kim mentions applying treatment to both ears, Kim does not provide different signals or different polarity to the opposite ears. Claim 16 is believed to be novel and non-obvious over Kim.

The number and type of claims in this application are within the original filing fee.

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Applicant respectfully requests further examination and that a timely Notice of Allowance be issued in this case.

Respectfully submitted,



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